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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,043

04/27/2005

Heimo Ylanen

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JAMES C. LYDON
100 DAINGERFIELD ROAD
SUITE 100
ALEXANDRIA, VA 22314

EXAMINER

WIESE, NOAH S

ART UNIT

PAPER NUMBER

1793

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DELIVERY MODE

05/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,043	Applicant(s) YLANEN ET AL.	
	Examiner NOAH S. WIESE	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/01/2005; 06/17/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The claims 12-22 are pending and presented for the examination.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/FI03/00715

Information Disclosure Statement (IDS)

3. The information disclosure statements (IDS) were submitted on 04/01/2005 and 06/17/2005. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner. Please refer to applicant's copy of the 1449 herewith.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 12-13, 16-18, and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brink et al (US 6054400).

Regarding **claim 12**, Brink et al teaches a bioactive glass composition that contains the same components of composition of claim 12. The components are taught in ranges that are broader than the ranges of claim 12, but encompass said ranges (see Brink claims 1 and 4, compositions reproduced below).

SiO ₂	53-60 wt-%
Na ₂ O	0-34 wt-%
K ₂ O	1-20 wt-%
MgO	0-5 wt-%
CaO	5-25 wt-%
B ₂ O ₃	0-4 wt-%
P ₂ O ₅	0.5-6 wt-%

SiO ₂	53-60 wt-%
Na ₂ O	0-19 wt-%
K ₂ O	1-17 wt-%
MgO	3-5 wt-%
CaO	5-22 wt-%
B ₂ O ₃	0-4 wt-%
P ₂ O ₅	0.5-6 wt-%

While the ranges taught by Brink are broader than those of the claim, they are not so broad as to make the Brink glasses materially different composition. Indeed, the Brink glasses are specifically taught to be of the same type as those of instant claims, that is, bioactive glasses. This indicates that the compositions of instant glasses are

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optimizations of the broader compositions of Brink, rather than materially different glasses. Therefore, glass compositions containing the components of instant claims in the claimed ranges could be obtained through the routine optimization and experimentation with the similar compositions taught by Brink.

The glass system on which the Brink glasses and those of instant claims are based, $\text{SiO}_2 - \text{Na}_2\text{O} - \text{CaO} - \text{P}_2\text{O}_5$, is a very well known system for bioglasses. See for example US 7040960, US 5648301, and US 5401693. Because it is well known in the art that successful bioglasses should contain the above components in the approximate ranges, and the Brink glasses broadly meet these known attributes, the experimentation and optimization of the Brink teachings would be very extensive. Thus, one of ordinary skill would have had motivation and ability to optimize the Brink glasses, and doing so would produce glasses meeting the limitations of claim 12. The claim is therefore obvious and not patentably distinct over the prior art of record.

Regarding **claim 13**, Brink teaches that the SiO_2 is optimally present in the amount of 54-56 wt% (see claim 5).

Regarding **claim 16**, Brink teaches that the glass compositions can be coated on a device (see column 4, lines 34-40).

Regarding **claim 17**, Brink teaches that the bioactive glass can be used in an implantable device (see column 5, lines 7-20).

Regarding **claim 18**, Brink teaches that the bioactive glasses can be used as fibers (see column 4, lines 34-40).

Regarding **claim 20**, Brink teaches that the bioactive glass can be made into a porous device (see column 4, lines 34-40). Brink does not explicitly teach how the porosity is introduced into the glass. However, this is a product-by-process limitation and as such, is not given patentable weight to the product claim 20. As shown above, Brink teaches bioactive glass compositions that can be routinely optimized to meet the limitations of instant claims and can be used in porous devices. Because Brink teaches all of the product limitations of claim 20, the additional process limitation does not render the claim patentably distinct over the prior art of record.

Regarding **claim 21**, Brink teaches that the bioactive glass can be used for tissue implants, which are tissue engineering devices (see column 4, lines 34-40).

7. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brink et al (US 6054400) in view of Bauer et al (US 5401693).

Regarding **claim 14**, the claim differs from Brink et al because Brink does not teach that alumina is included in the bioactive glasses. However, the use of alumina in these types of bioactive glass systems was known in the art at the time the invention was filed.

Bauer et al teaches glass fibers made from bioactive glass. As discussed above, the glasses taught in Bauer are of the same SiO_2 - Na_2O - CaO - P_2O_5 system as those of Brink et al. Bauer further teaches that small amounts of Al_2O_3 are present in the bioactive glass composition (see column 6, lines 25-34). The Al_2O_3 acts as a network former in the bioglasses, which leads to increased strength and resiliency (see column 3, lines 29-39). One of ordinary skill in the art would have been motivated to include the

small amount of Al_2O_3 in the Brink glass if small increases in strength properties were desired. The teachings of Bauer et al show that this inclusion was known in the same type of bioactive glass system as is used in Brink, so reasonable success would be expected. The modification of Brink in view of Bauer would lead one of ordinary skill to include Al_2O_3 in amounts of less than 1 wt% to the Brinks glasses. Therefore, claim 14 is obvious and not patentably distinct over the prior art of record.

Regarding **claim 15**, it would be obvious to one of ordinary skill that a decrease in Na_2O or K_2O could be replaced by Al_2O_3 or B_2O_3 , given the teachings of Brink and Bauer.

8. Claims 19 and 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brink et al (US 6054400) in view of Young et al (US 3904425).

Regarding **claim 22**, Brink et al teaches that the glasses are made by melting the batch to a temperature of 1300-1600°C, cooling, and then remelting the batch at the same temperature (see column 6, lines 45-55). Brink teaches that the glasses can be crushed between heatings (see column 4, lines 34-40 and column 14, lines 58-62). Claim 22 differs from Brink et al because Brink does not teach the time at which the glass is held at the elevated temperatures (fining), or the time at which the glass is left at ambient temperature between heatings. However, these times were known in the art at the time the invention was filed.

Young et al teaches a method of producing glasses comprising melting the glass batch, fining at a temperature of 1371°C for 1-3 hours, and then cooling the glass to room temperature overnight (see column 3, lines 58-66). While the composition of the

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Young glass is somewhat different than that of the Brink glasses, the Young glass contains many of the same elements and is similar enough that the methods are analogous. One of ordinary skill would have been motivated to take the fining and cooling times from the Young method because these times are not taught specifically by Brink, which would cause one to look elsewhere for the variables. Young teaches a method for preparing glasses similar to the Brink glasses and melted at similar temperatures, and so one would be motivated to use Young for modification. The temperatures and melting times taught by Young are used because they are adequate for the homogenous melting, fining, and casting of the glass composition. These are advantageous effects that one would seek when creating a practical method for the Brink glasses. The modification of Brink in view of Young teaches all of the method limitations of claim 22, and thus the claim is obvious and not patentably distinct over the prior art of record.

Regarding **claim 19**, the claim differs from Brink et al because Brink does not explicitly teach that the glass can be formed into a sheet. But forming sheets of glass compositions is well known in the glass arts. The teachings of Young show that forming glass sheets is well known (see columns 3-4, lines 65-17). One would have been motivated to form a sheet from the Brink glasses because this configuration would be useful for substrates or for testing samples, the purpose for which the sheets are used in the Young patent. Thus, forming a sheet from the Brink glass compositions would have been obvious to one of ordinary skill in the art, and the claim is patentably indistinct over the prior art of record.

Conclusion

9. No claim is allowed.
10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noah S. Wiese whose telephone number is 571-270-3596. The examiner can normally be reached on Monday-Friday, 7:30am-5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on 571-272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry A Lorengo/
Supervisory Patent Examiner, Art Unit 1793

Noah Wiese
May 15th, 2008

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